

## **REMARKS**

1. In response to the Office Action mailed October 4, 2007, Applicants respectfully request reconsideration. Claims 1-4, 6, 8-10, 12, 13, 22-25 and 36-43 were last presented in the application. In the outstanding Office Action, claims 1-4, 6, 8-10, 12, 13, 22-25 and 36-43 were rejected. In this paper, no claims have been cancelled, amended or added. Thus, upon entry of this paper, claims 1-4, 6, 8-10, 12, 13, 22-25 and 36-43 will be pending in this application.
2. Based upon the following Remarks, Applicants respectfully request that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

### ***Specification Corrections***

3. Applicants thank the Examiner for acknowledging that the corrections to the specification submitted on July 9, 2007 were sufficient to over the objections made in the previous Office Action.

### ***Claim Objections***

4. Applicants thank the Examiner for acknowledging that the amendments submitted on July 9, 2007 were sufficient to over the objections to the claims made in the previous Office Action.

### ***Claim Rejections under 35 USC §112***

5. Applicants thank the Examiner for acknowledging that the amendments submitted on July 9, 2007 were sufficient to over the rejections under 35 USC § 112, second paragraph, made in the previous Office Action.

### ***Claim Rejections under §103(a) - Kuzma in view of Dutcher***

6. Claims 1-4, 6, 8-10, 13, 22, 25, 36-39, and 41-43 were rejected under 35 U.S.C. 103(a) as being obvious over WO 00/69513 to Kuzma (“Kuzma”) in view of U.S. Patent No. 5,153,090 to Dutcher (“Dutcher”). Specifically, the Examiner asserts that “Kuzma discloses the same invention as claimed” but admits that Kuzma “does not disclose an anchor configured to prevent

rotation.” (See, Office Action, pg. 3, paragraph 7.) The Examiner then asserts that “Dutcher teaches using a porous polyester fiber mesh” and that “it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the mesh material of Dutcher with the device of Kuzma.” The alleged motivation is that such a combination would “enhanc[e] tissue ingrowth to firmly fix the lead to target tissue.” (See, Office Action, pgs. 3-5, paragraph 7.) Applicants respectfully traverse the rejections for at least the following reasons.

7. The MPEP states, in part:

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to...

- (B) The *references must be considered as a whole and must suggest the desirability and thus the obviousness* of making the combination;
- (C) The *references must be viewed without* the benefit of *impermissible hindsight* vision afforded by the claimed invention;

(See, Manual of Patent Examining Procedures, §2141(II), entitled “Basic Considerations Which Apply To Obviousness Rejections”; emphasis added.)

8. Kuzma states, “thus, it is seen that the array 10 is held in position within the basal region 34 by the shoulder 19, and flaps or tines 16. Moreover, because the electrode array 10 is “flattened”, or pancake shaped (when viewed in cross section as seen in FIG. 3), the distal tip 13 and the rest of the array 10 readily slide through the slit 42. The *slit 42 advantageously maintains the medial side of the array 10 facing in the right direction.*” (See, Kuzma, pg. 8, ll. 23-28.) The “slit 42” in Kuzma refers to a slit “made in the round window membrane 40”, as illustrated in FIG. 2 of Kuzma. Clearly, Kuzma discloses that the array is “flattened” and “pancake shaped” (when viewed in cross section) and that this flattened tip slides through the “slit” that has been surgically made in the round window membrane of the patient. Kuzma discloses that this flat-array inserted through slit 42 “advantageously maintains the medial side of the array 10 facing in the right direction.” In other words, the flat array, in cooperation with an appropriately shaped incision formed by a surgeon, is described as preventing the device Kuzma array from rotating.

9. Thus, Kuzma teaches an arrangement of a surgical incision and a flat-shaped array that together function to prevent rotation. As such, Kuzma does not teach Applicants’ claimed

anchor for preventing rotation, as acknowledged by the Examiner. (*See, Office Action, pg. 3, paragraph 7.*) Since the Examiner has not indicated that the arrangement of Kuzma of the surgical incision and the flat-shaped array described above would be deficient, inadequate or otherwise lacking in providing the function of preventing rotation, one of ordinary skill in the art would not have been motivated to seek out an additional component or arrangement to provide anti-rotation such as in Dutcher.

10. Additionally, Kuzma does not teach or suggest the use of an additional or secondary structure or arrangement, such as Applicants' anchor, for preventing rotation. Accordingly, one of ordinary skill in the art would not be motivated to seek out a reference which teaches an additional anti-rotation structure. In fact, by combining the references as proposed, it would only be adding a feature that is performing a function which is already being performed by the arrangement described above, namely the preventing of rotation by the electrode array when it is inserted into the cochlea. The Examiner's adding to an otherwise complete reference with respect to an anti-rotation feature by suggesting the adding of a redundant anti-rotation feature from Dutcher can only be viewed as a use of impermissible hindsight, contrary to the requirements of the MPEP, for example, as quoted above. Accordingly, Applicants assert that this rejection of these claims is improper and respectfully request that it be reconsidered and withdrawn.

11. Furthermore, Applicants disagree with the Examiner's assertion that one of ordinary skill in the art would have been motivated to combine Kuzma with Dutcher "for the purpose of enhancing tissue ingrowth to firmly fix the lead to target tissue." (*See, Office Action, pgs. 3-5, paragraph 7.*) In Kuzma, the array is already firmly fixed by shoulder 19 and flaps/tines 16, which prevents translation, and by the combination of the surgical slit 42 working with the flat-shaped array 10, which prevents rotation. Utilizing an anchor having an ingrowth of tissue to firmly fix the carrier member is an approach taken by Applicants to prevent rotation and translation. Given the approach taken by Kuzma, there is no other benefit from an ingrowth of tissue to the device of Kuzma since rotation and translation are already prevented by the surgical slit and flat-shaped array and by the shoulder and flaps/tines, as described above. In other words, the benefits attained by an ingrowth of tissue is already achieved by the device of Kuzma without any ingrowth of tissue. Accordingly, one of ordinary skill in the art would not have been

motivated by Kuzma to seek a reference which described an “ingrowth of tissue to firmly fix the lead to the target tissue” as asserted by the Examiner.

12. Even were the Examiner’s assertions as to the motivation of combining Kuzma with Dutcher proper, the resulting device would not teach or suggest Applicants’ claimed invention without substantial modification to Kuzma. For instance, because Kuzma is configured to prevent translation using the protuberances 16 of FIG. 2, and to prevent rotation using the cooperation of flat array 12 and slit 42 of FIGS. 2 and 4, it is unclear where an anchor as claimed by Applicants would be placed on the Kuzma device. Assuming for the sake of argument that it could be mounted on shoulder 19 shown in FIG. 2 of Kuzma, substantial modifications would have to be made to the Kuzma device in order to make those features added by the Examiner provide the anti-rotation benefit. For example, as shown in FIG. 5, the Kuzma device is designed to be insertable at an angle such that the full surface of shoulder 19 does not contact the round window membrane 40. In that case, the anchor added to shoulder 19 of Kuzma would not be in contact with round window membrane 40 so as to be able to prevent rotation unless tines 16 are removed/modified and shoulder 19 redesigned so that an anchor on shoulder 19 is in contact with round window membrane 40 (e.g., by increasing the thickness of a portion of shoulder 19). For at least these reasons, Applicants assert that no motivation exists for combining Kuzma with Dutcher and that even if proper the combination would not result in Applicants’ claimed invention without requiring significant modification of the Kuzma device. Therefore, the combination suggested by the Examiner is improper, and Applicants’ respectfully request that these rejections be reconsidered and that they be withdrawn.

13. Independent claims 22 and 38 contain similar language and limitations as independent claim 1, and are patentable for the same reasons discussed above which render claim 1 patentable over the above and other evidence of record.

#### ***Dependent Claims***

14. The dependent claims incorporate all of the subject matter of their respective independent claims and add additional subject matter which makes them a *fortiori* independently patentable over the art of record. Accordingly, Applicants respectfully request that the outstanding rejections of the dependent claims be reconsidered and withdrawn.

***Conclusion***

In view of the foregoing, this application should be in condition for allowance. A notice to his effect is respectfully requested.

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Respectfully submitted,

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